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PATENT
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Client Ref. No.: OBM77CIP

TOWNSEND and TOWNSEND and CREW LLP

By: Patricia Skottor

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re application of:

Peter L. Stern, et al.

Application No.: 10/520,502

Filed: January 3, 2005

For: 5T4 ANTIGEN EXPRESSION

Customer No.: 20350

Confirmation No. 2720

Examiner: NOBLE, Marcia Stephens

Technology Center/Art Unit: 1632

RESPONSE TO RESTRICTION
REQUIREMENT

Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

Sir:

This is in reply to the Restriction Requirement mailed February 13, 2006, which set March 13, 2006 as the initial deadline for response. A Petition for a two-month extension of time, until May 13, 2006 is enclosed herewith, and this Response is believed to be timely filed, and no fees are believed to be due.

Reconsideration of the Requirement in light of the following amendments and remarks is respectfully requested.

The Requirement mailed February 13, 2006 alleged proper restriction among claims 1-20 in the instant application. But the instant application was filed with a Preliminary Amendment, dated January 3, 2005, which revised claims 5-7, 10, and 13-15 along with the cancellation of claim 20.

The undersigned's review of the instant application's Image File Wrapper (IFW) at the U.S. Patent and Trademark Office website on May 9, 2006 indicated that the Preliminary Amendment was entered and electronically in advance of the Restriction Requirement.

Therefore, Applicants respectfully submit that the Requirement mailed February 13, 2006 is inaccurate and misplaced.

Nevertheless, and in the interest of advancing prosecution, Applicants have compared the asserted Restriction Requirement to pending claims 1-19. Applicants believe that should the Requirement be maintained, it would correspond to the pending claims via the Groupings alleged in the original Requirement:

Group I:	claims 1-6, 8, and 14
Group II:	claims 1-5, and 7
Group III:	claims 9 and 10
Group IV:	claims 11, 13, and 15
Group V:	claim 12 (because claim 13 no longer depends from claim 12)
Group VI:	deleted (see remarks below)
Group VII:	claims 16-18
Group VIII:	claim 19

As an initial matter, Applicants point out that the characterization of Group III of the Restriction Requirement as “a method of sorting stem cells by differentiation status using an antibody recognizing 5T4 antigen by using a reporter assay” is misplaced. Claims 9 and 10 do not relate or refer to a reporter assay.

Additionally, Applicants also point out that the inclusion of claim 13 in Group V appeared to be due to its original dependency from claim 12. That dependency was removed by the Preliminary Amendment, and so claim 13 does not belong in Group V.

Moreover, Applicants point out that Group VI should not exist as it is based on the same subject matter as that of Group III, but includes claims drawn to the subject matter of Group IV. Therefore, Applicants respectfully submit that claim 15 should not be separated from claims 11 and 13 of Group IV.

Applicants have carefully reviewed the statement of the Restriction Requirement and respectfully traverse as follows.

Contrary to the assertions in the Requirement, the claims of the alleged Groups are linked via the same or corresponding special technical feature. In fact, the special technical feature linking all of these groups is the detection of the differentiation status of stem cells through 5T4 antigen detection. This special technical feature is present through the corresponding claim elements such as antibody detection (Group I, claims 1-6, 8, 14) or reporter gene detection (Group II, claims 1-5, and 7). Furthermore, the method of sorting stem cells (Group III, claims 9 and 10) intrinsically requires the application of the detection method (or detection step, e.g., binding of a 5T4 antibody to 5T4 antigen).

Moreover, and contrary to the allegation in the Requirement, the special technical feature present in the claims is not anticipated by the cited Southall et al. document. The cited document discloses a diagnostic assay using an antibody for distinguishing cancer tissue from normal tissue. The Examiner alleges that this method is the same as the claimed invention because "most carcinomas are characteristically clonal and undifferentiated, they can be considered stem cells". Applicants strongly traverse because, and in sharp contrast to the allegation, stem cells and cancer cells are substantially and significantly different in their differentiation potential.

Stem cells can differentiate into multiple cell types, and in the case of pluripotent stem cells into essentially all cell types found in the adult organism. Cancer cells, while they appear undifferentiated, have no such potential. Furthermore, it has long been known that antigens which are found specifically on cancer cells are not found on embryonic stem cells and vice versa. Therefore, the identification of a marker antigen on a cancer cell as disclosed by Southall et al. does not include or suggest the appearance of the same marker antigen on a stem cell.

Additionally, 5T4 is expressed differently between differentiated stem cells and pluripotent stem cells such that its expression can be used to differentiate between the two. This is evident by a comparison of claims 1 and 2. Accordingly, the diagnostic assay disclosed by Southall et al. and the methods of the claimed invention are substantially and significantly

different as they are directed to divergent cell types (cancer cells in Southall et al. and stem cells in the pending claims). Indeed, the specification sets forth this distinction in the Background section.

In light of the foregoing, all of the claims share the same special technical feature because all the claims relate to detecting the differentiation status of stem cells through 5T4 antigen expression. Accordingly, Applicants request reconsideration and withdrawal of the Restriction Requirement for the reasons provided above. In the very least, Applicants request the examination of the claims of Groups I and III because the claimed method of Group III require the claimed method of detection of Group I and would therefore impose no additional search burden.

The Restriction Requirement further asserts that the “application contains claims directed to more than one species of the generic invention.” The Requirement alleges that the “species are deemed to lack unity of invention because they are not so linked... under PCT Rule 13.1.” Applicants respectfully point out that Rule 13.1 provides no basis for an election of species but rather allows claims directed to the same “general inventive concept” to be examined together. As discussed above, the “general inventive concept”, or “special technical feature”, of the claims is that of using 5T4 antigen to detect the differentiation status of stem cells. This reflects a genus of methods defined by the detection of 5T4 expression on stem cells as an indicator of differentiation status.

Applicants respectfully submit that a Requirement for an election of species from the genus of methods must be based upon 37 C.F.R. § 1.141(a) and 1.146, both of which expressly recognize that “a reasonable number” of species may be claimed along with an allowable generic claim within a single application. Applicants further point out that there has been no demonstration that “more than a reasonable number of species” is encompassed by the pending claims. For example, claim 5 enumerates merely eight different stem cell sources, and no basis has been provided to demonstrate that eight sources is an unreasonable number of species. Applicants therefore traverse the Requirement because no more than a reasonable number of species is presented in the pending claims.

Moreover, and as set forth at 37 C.F.R. § 1.146, election of a species is discretionary and results in a restriction *only* “if no claim to the genus is found to be allowable.” Thus Applicants respectfully submit that the requirement for an election of species is for purposes of facilitating search and examination. If no prior art is found to anticipate or render obvious the elected species, Applicants respectfully submit that the search of the claims should be extended to the next species to allow for consideration of the generic claim encompassing the species.

Based on the above, Applicants respectfully submit that the Requirement for an election of species is misplaced and should be modified or withdrawn.

In the event that the Restriction Requirement is maintained, Applicants elect Group I, claims 1-6, 8, and 14, with traverse for the reasons provided above, and the species of “human” as the source of the stem cells.

Applicants respectfully submit that elected claims 1-6, 8 and 14 are generic to the elected species.

If the Examiner believes a telephone conference would expedite prosecution of this application, please telephone the undersigned at 858-350-6100.

Respectfully submitted,



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